K031651

Revision August 2003 Item 9.1

AUG 13 2003

curasan

# Special 510 (K) Summary:
# Line Extension to Cerasorb™ ORTHO (granular form)

**Submission Information:**

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|---|---|
| Name and Address of the Sponsor: | curasan AG<br>Lindigstrasse 4<br>D – 63801 Kleinostheim, Germany |
| Contact person: | Dr. Rolf Kaufmann,<br>Regulatory Affairs Manager Cerasorb<br>Tel.: ++49 – 6027 – 468653<br>Fax: ++49 – 6027 – 468633<br>E – mail: Rolf.Kaufmann@curasan.de |
| Registered U. S. agent: | Dr. Eric Wiechert<br>109 Shore Drive<br>Garner, NC 27529<br>USA<br>phone: 919 – 7728518, fax: 919 - 7721300<br>E – mail: ewiecher@bellsouth.net |

**Device Identification:**

| | |
|---|---|
| Proprietary Name: | Cerasorb™ ORTHO |
| Common Name: | Bone Void Filler |
| Classification: | Unclassified |

**Predicate Devices:**

Cerasorb™ ORTHO (granular form): Bone void filler consisting of pure phase Beta-Tricalcium Phosphate.

ChronOs: Bone void filler, granules and block forms consisting of Beta-Tricalcium Phosphate

Vitoss Scaffold Synthetic: Bone void filler, granules and block forms consisting of Beta-Tricalcium Phosphate

**Description of the Device Modification:**

The device modification is a change in the size resp. geometry of the bone void filler. The predicate device Cerasorb™ ORTHO, a synthetic, porous, resorbable and osteoconductive bone void filler, was developed in granular form (spherical granules) of different diameter (500-1000µm, 1000-2000µm) to be filled in the bone void(s). The material consists of pure phase Beta-Tricalcium Phosphate of interconnecting porosity. This submission is intended to address a modification in the shape of the bone void filler. The bone void filler is now additionally presented as block forms of different geometry (for example wedge, cylinder, cube, parallelepiped) and in different sizes up to 30cc. The basic pure phase Beta-Tricalcium Phosphate material is also of interconnecting microporosity. Straight through macropores of different size (500–2000µm) are mechanically introduced by drilling.

**Intended Use:**

Cerasorb™ ORTHO (granular or block forms) is intended for use as a bone void filler in voids or gaps (resulting from surgery, trauma or degenerative processes) in the skeletal system (extremities, spine, pelvis) that are not intrinsic to the stability of the bony structure. Following placement in the bony void or gap, the β-TCP ceramic material is gradually resorbed and replaced with bone. The placement of Cerasorb™ ORTHO should not be in dry form, the material should be mixed with autologous blood.

**Statement of technological comparison**

All design modifications consist of pure phase Beta-Tricalcium Phosphate ceramic material according to ASTM F 1088-87, reapp. 1992. The material is porous, osteoconductive and resorbable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 2003

Dr. Rolf Kaufmann
Regulatory Affairs Manager Cerasorb
Curasan AG
Lindigstrasse 4
63801 Kleinostheim
Germany

Re: K031651
Trade Name: Cerasorb ORTHO
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: July 16, 2003
Received: July 18, 2003

Dear Dr. Wiechert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

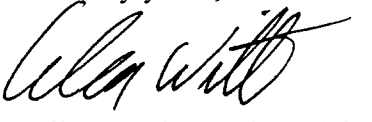
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031651

Device Name: Cerasorb™ ORTHO

Indications for Use:

Cerasorb™ ORTHO (granular or block forms) is intended for use as a bone void filler in voids or gaps (resulting from surgery, trauma or degenerative processes) in the skeletal system (extremities, spine, pelvis) that are not intrinsic to the stability of the bony structure. Following placement in the bony void or gap, the ß-TCP ceramic material is gradually resorbed and replaced with bone. The placement of Cerasorb™ ORTHO should not be in dry form, the material should be mixed with autologous blood.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurence of CDRH, Office of Device Evaulation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K031651

(Optional Format 3-10-98)